HOUSE BILL No. 1382

DIGEST OF INTRODUCED BILL

Citations Affected: IC 5-10-8-15; IC 12-15-5-9; IC 27-8-25; IC 27-13-7-20.

Synopsis: Insurance coverage for clinical trials. Requires coverage for certain services related to clinical trials under a state employee health plan, the state Medicaid program, a policy of accident and sickness insurance, and a health maintenance organization contract.

Effective: July 1, 2009.

Welch, Brown C, Brown T

January 13, 2009, read first time and referred to Committee on Public Health.

Introduced

First Regular Session 116th General Assembly (2009)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2008 Regular Session of the General Assembly.

HOUSE BILL No. 1382

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 5-10-8-15 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: **Sec. 15. (a) As used in this section, "care method" means the use of a particular drug or device in a particular manner.**

(b) As used in this section, "clinical trial" means a Phase I, II, III, or IV research study:

(1) that is conducted:

(A) using a particular care method to prevent, diagnose, or treat a cancer or another serious or life threatening disease for which:

(i) there is no clearly superior, noninvestigational alternative care method; and

(ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;

(B) in a facility where personnel providing the care method

to be followed in the research study have:

(i) received training in providing the care method;

(ii) expertise in providing the type of care required for the research study; and

(iii) experience providing the type of care required for the research study to a sufficient volume of patients to maintain expertise; and

(C) to scientifically determine the best care method to prevent, diagnose, or treat the cancer or other serious or life threatening disease; and

(2) that is:

(A) exempt from the federal Food and Drug Administration's investigational new drug or device application requirement as provided under 21 CFR 312 or 21 CFR 812; or

(B) approved or funded by one (1) of the following:

(i) A National Institutes of Health institute.

(ii) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(iii) The federal Food and Drug Administration.

(iv) The United States Department of Veterans Affairs.

(v) The United States Department of Defense.

(vi) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(vii) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.

(c) As used in this section, "covered individual" means an individual entitled to coverage under a state employee health plan.

(d) As used in this section, "routine care cost" means the cost of medically necessary services related to the care method that is under evaluation in a clinical trial. The term does not include the following:

(1) The drug or device that is under evaluation in a clinical trial.

(2) Items or services that are:

(A) provided solely for data collection and analysis and not in the direct clinical management of an individual enrolled

in a clinical trial;

(B) customarily provided at no cost by a research sponsor to an individual enrolled in a clinical trial; or

(C) provided solely to determine eligibility of an individual for participation in a clinical trial.

(e) As used in this section, "state employee health plan" means one (1) of the following:

(1) A self-insurance program established under section 7(b) of this chapter to provide group health coverage.

(2) A contract with a prepaid health care delivery plan that is entered into or renewed under section 7(c) of this chapter.

(f) A state employee health plan that provides coverage for basic health care services shall provide coverage for routine care costs related to a clinical trial for a covered individual participating in the clinical trial.

SECTION 2. IC 12-15-5-9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: **Sec. 9. (a) As used in this section, "care method" means the use of a particular drug or device in a particular manner.**

(b) As used in this section, "clinical trial" means a Phase I, II, III, or IV research study:

(1) that is conducted:

(A) using a particular care method to prevent, diagnose, or treat a cancer or another serious or life threatening disease for which:

(i) there is no clearly superior, noninvestigational alternative care method; and

(ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;

(B) in a facility where personnel providing the care method to be followed in the research study have:

(i) received training in providing the care method;

(ii) expertise in providing the type of care required for the research study; and

(iii) experience providing the type of care required for the research study to a sufficient volume of patients to maintain expertise; and

(C) to scientifically determine the best care method to prevent, diagnose, or treat the cancer or other serious or life threatening disease; and

(2) that is:

(A) exempt from the federal Food and Drug Administration's investigational new drug or device application requirement as provided under 21 CFR 312 or 21 CFR 812; or

(B) approved or funded by one (1) of the following:

(i) A National Institutes of Health institute.

(ii) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(iii) The federal Food and Drug Administration.

(iv) The United States Department of Veterans Affairs.

(v) The United States Department of Defense.

(vi) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(vii) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.

(c) As used in this section, "routine care cost" means the cost of medically necessary services related to the care method that is under evaluation in a clinical trial. The term does not include the following:

(1) The drug or device that is under evaluation in a clinical trial.

(2) Items or services that are:

(A) provided solely for data collection and analysis and not in the direct clinical management of an individual enrolled in a clinical trial;

(B) customarily provided at no cost by a research sponsor to an individual enrolled in a clinical trial; or

(C) provided solely to determine eligibility of an individual for participation in a clinical trial.

(d) The Medicaid program shall provide coverage for routine care costs related to a clinical trial for a recipient participating in the clinical trial.

(e) The office shall apply to amend the state Medicaid plan if the office determines that an amendment is necessary to carry out this section.

SECTION 3. IC 27-8-25 IS ADDED TO THE INDIANA CODE AS

A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]:

Chapter 25. Coverage for Care Related to Clinical Trials

Sec. 1. As used in this chapter, "care method" means the use of a particular drug or device in a particular manner.

Sec. 2. As used in this chapter, "clinical trial" means a Phase I, II, III, or IV research study:

(1) that is conducted:

(A) using a particular care method to prevent, diagnose, or treat a cancer or another serious or life threatening disease for which:

(i) there is no clearly superior, noninvestigational alternative care method; and

(ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;

(B) in a facility where personnel providing the care method to be followed in the research study have:

(i) received training in providing the care method;

(ii) expertise in providing the type of care required for the research study; and

(iii) experience providing the type of care required for the research study to a sufficient volume of patients to maintain expertise; and

(C) to scientifically determine the best care method to prevent, diagnose, or treat the cancer or other serious or life threatening disease; and

(2) that is:

(A) exempt from the federal Food and Drug Administration's investigational new drug or device application requirement as provided under 21 CFR 312 or 21 CFR 812; or

(B) approved or funded by one (1) of the following:

(i) A National Institutes of Health institute.

(ii) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(iii) The federal Food and Drug Administration.

(iv) The United States Department of Veterans Affairs.

(v) The United States Department of Defense.

(vi) The institutional review board of an institution

located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(vii) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.

Sec. 3. As used in this chapter, "covered individual" means an individual entitled to coverage under a policy of accident and sickness insurance.

Sec. 4. As used in this chapter, "policy of accident and sickness insurance" has the meaning set forth in IC 27-8-5-1. The term does not include the following:

(1) Accident only, credit, dental, vision, Medicare, Medicare supplement, long term care, or disability income insurance.

(2) Coverage issued as a supplement to liability insurance.

(3) Automobile medical payment insurance.

(4) A specified disease policy.

(5) A limited benefit health insurance policy.

(6) A short term insurance plan that:

(A) may not be renewed; and

(B) has a duration of not more than six (6) months.

(7) A policy that provides a stipulated daily, weekly, or monthly payment to an insured during hospital confinement, without regard to the actual expense of the confinement.

(8) Worker's compensation or similar insurance.

(9) A student health insurance policy.

Sec. 5. As used in this chapter, "routine care cost" means the cost of medically necessary services related to the care method that is under evaluation in a clinical trial. The term does not include the following:

(1) The drug or device that is under evaluation in a clinical trial.

(2) Items or services that are:

(A) provided solely for data collection and analysis and not in the direct clinical management of an individual enrolled in a clinical trial;

(B) customarily provided at no cost by a research sponsor to an individual enrolled in a clinical trial; or

(C) provided solely to determine eligibility of an individual for participation in a clinical trial.

Sec. 6. A policy of accident and sickness insurance shall provide

coverage for routine care costs related to a clinical trial for a covered individual participating in the clinical trial.

SECTION 4. IC 27-13-7-20 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: **Sec. 20. (a) As used in this section, "care method" means the use of a particular drug or device in a particular manner.**

(b) As used in this section, "clinical trial" means a Phase I, II, III, or IV research study:

(1) that is conducted:

(A) using a particular care method to prevent, diagnose, or treat a cancer or another serious or life threatening disease for which:

(i) there is no clearly superior, noninvestigational alternative care method; and

(ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;

(B) in a facility where personnel providing the care method to be followed in the research study have:

(i) received training in providing the care method;

(ii) expertise in providing the type of care required for the research study; and

(iii) experience providing the type of care required for the research study to a sufficient volume of patients to maintain expertise; and

(C) to scientifically determine the best care method to prevent, diagnose, or treat the cancer or other serious or life threatening disease; and

(2) that is:

(A) exempt from the federal Food and Drug Administration's investigational new drug or device application requirement as provided under 21 CFR 312 or 21 CFR 812; or

(B) approved or funded by one (1) of the following:

(i) A National Institutes of Health institute.

(ii) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(iii) The federal Food and Drug Administration.

(iv) The United States Department of Veterans Affairs.

(v) The United States Department of Defense.

(vi) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(vii) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.

(c) As used in this section, "routine care cost" means the cost of medically necessary services related to the care method that is under evaluation in a clinical trial. The term does not include the following:

(1) The drug or device that is under evaluation in a clinical trial.

(2) Items or services that are:

(A) provided solely for data collection and analysis and not in the direct clinical management of an individual enrolled in a clinical trial;

(B) customarily provided at no cost by a research sponsor to an individual enrolled in a clinical trial; or

(C) provided solely to determine eligibility of an individual for participation in a clinical trial.

(d) An individual contract or a group contract that provides coverage for basic health care services shall provide coverage for routine care costs related to a clinical trial for an enrollee participating in the clinical trial.

SECTION 5. [EFFECTIVE JULY 1, 2009] **(a) IC 5-10-8-15, as added by this act, applies to a state employee health plan that is established, entered into, issued, delivered, amended, or renewed after June 30, 2009.**

(b) IC 12-15-5-9, as added by this act, applies to a Medicaid risk based managed care contract that is entered into, delivered, amended, or renewed after June 30, 2009.

(c) IC 27-8-25, as added by this act, applies to a policy of accident and sickness insurance that is issued, delivered, amended, or renewed after June 30, 2009.

(d) IC 27-13-7-20, as added by this act, applies to an individual contract or a group contract that is entered into, delivered, amended, or renewed after June 30, 2009.

(e) This SECTION expires July 1, 2014.